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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/021,425	10/30/2001	Suzanne L. Bolten	3196/00 US	2066
26648	7590	08/30/2004	EXAMINER	
PHARMACIA CORPORATION GLOBAL PATENT DEPARTMENT POST OFFICE BOX 1027 ST. LOUIS, MO 63006			PATTERSON, CHARLES L JR	
			ART UNIT	PAPER NUMBER
			1652	

DATE MAILED: 08/30/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/021,425	Applicant(s) SUZANNE ET AL.	
	Examiner Charles L. Patterson, Jr.	Art Unit 1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02 June 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 2-10, 12, 13, 15-56 and 58-83 is/are pending in the application.
 4a) Of the above claim(s) 3-9, 30-34, 36-45, 50-56 and 59-77 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 2, 27, 58, 78 and 79 is/are allowed.
- 6) ☒ Claim(s) 10, 12, 13, 15-26, 28, 29, 35, 46-49 and 80-83 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 30 October 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

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| <p>1) <input type="checkbox"/> Notice of References Cited (PTO-892)</p> <p>2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)</p> <p>3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
 Paper No(s)/Mail Date _____.</p> | <p>4) <input type="checkbox"/> Interview Summary (PTO-413)
 Paper No(s)/Mail Date. _____.</p> <p>5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)</p> <p>6) <input type="checkbox"/> Other: _____.</p> |
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The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 10, 12-13, 15-26, 28-29, 35, 46-49 and 80-83 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for nucleic acids of SEQ ID NO:1 or that hybridize under high stringency conditions to SEQ ID NO:1, does not reasonably provide enablement for claims of the scope of the instant claims. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims. This rejection is repeated for the reasons given in the last action. Applicants arguments have been carefully considered but do not overcome the instant rejection. This rejection is repeated for the reasons given in the last action. Applicants arguments have been carefully considered but do not overcome the instant rejection.

On page 11 of applicants' reply six pages and line numbers in the specification are referred to. Apparently applicants are using another version of the specification as the examiner cannot find what is indicated at these pages and lines. For example, Example 20 is stated to be on page 60, line 29 to page 62, line 19, when in the specification submitted for prosecution it is on page 67, line 12 to page 69, line 8. Applicants also state that "[t]he selective activity demonstrated in Example 20 is aligned with that activity shown in Dutta, et al. (page 3, lines 27-29)." There is no indication as to what "Dutta, et al." refers to but the examiner has found such a reference in the IDS filed 7/11/03. However there is no "page 3" in this reference. The

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reference teaches that spores of *Aspergillus ochraceus* will transform progesterone into its 11 α -hydroxy derivative. It is not known what is meant by "aligned with that activity".

Applicants state that "[a]ndrostenedione is properly classified as a 3 keto delta 4,5 steroid" but offer no proof of this statement. They then state that "[t]he structure of androstenedione is also known (page 18, line 6)", but as stated *supra*, the information referred to here is not at that page and line. They also state that "[o]ne of skill in the art is in the possession of standard steroid carbon numbering schema" and offer a reference showing this. The examiner agrees that the ordinary artisan knows the steroid numbering scheme but as applicants offer no convincing proof as to the structure of androstenedione or that it is a 3 keto delta 4,5 steroid, the examiner cannot further evaluate these statements or the instant claims in view of them.

The examiner has dropped claim 2, 27, 58 and 78-79 from the instant 35 USC § 112 first paragraph rejection because they are drawn to SEQ ID NO:1 or 2, or nucleic acid that hybridize under highly stringent conditions to SEQ ID NO:1. Claims 80-83 are drawn to nucleic acids that are outside these limitations. It is noted that claim 83 reads on any number whatsoever of conservative substitutions.

It is continued to be maintained that one of ordinary skill in the art would not be taught by the instant specification to make and/or use nucleic acids of the scope of the instant claims without undue experimentation.

Claims 2, 27, 58 and 78-79 are allowed.

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THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Charles L. Patterson, Jr., PhD, whose telephone number is 571-272-0936. The examiner can normally be reached on Monday - Friday from 7:30 to 4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapura Achutamurthy, can be reached on 571-272-0928. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the

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Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Charles L. Patterson, Jr.
Primary Examiner
Art Unit 1652

Patterson
August 24, 2004

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